WIC Non-Contract Formula and Supplemental Foods Medical Documentation Policy

WIC Program Cost Containment

The Alaska WIC Program provides infant formulas through a bulk-purchasing contract, saving WIC money. WIC encourages Health Care Providers (HCP) to prescribe contract formulas for formula-fed WIC infants. When a WIC participant needs a non-contract formula due to diagnosed serious medical conditions, the HCP must request it using the Enteral Nutrition Prescription Request (ENPR) form. General symptoms such as fussiness, colic, spitting up, constipation, etc. are not acceptable justification for a non-contract formula. While a HCP and/or a parent or guardian may feel that a non-contract formula is appropriate in some of these situations, funding constraints and WIC regulations limit the issuance of non-contract formulas only to participants with serious medical conditions. Contract formulas Similac Advance Early Shield, Isomil Advance Soy, Similac Sensitive and Similac Go & Grow-Soy can be provided to children over 1 year, with a documented medical need. Ready to feed (RTF) formula may be authorized when the Competent Professional Authority (CPA) determines and documents that there is an unsanitary or restricted water supply, poor refrigeration or the person caring for an infant my have difficulty in correctly diluting concentrated liquid or powdered formula (CFR 246.10c.1.i).

Changes in Required Medical Documentation due to The New WIC Food Packages (NFP) Rule Review New WIC Food Packages Summary of Changes to Medical Documentation http://www.nal.usda.gov/wicworks/Learning_Center/FP/Overview_MedDoc.pdf handout.

Changes to medical documentation requirements as a result of the new WIC Food Packages Rule include:

- Providing the amount of formula needed per day
- Prescribing supplemental food(s) authorized for the participants' qualifying conditions and the amounts prescribed. (See Food Package III, IV, V, VI and VII)

At this time, Food Package III (FPG III) is prescribed to women and children with a serious medical condition that requires an exempt infant formula or WIC eligible medical food. It provides formula, cereal and juice only. The New WIC Food Package Interim Rule (CFR 246.10(d) expands FPG III to infants with a serious medical condition that requires an exempt infant formula or WIC eligible medical food and it includes the medical prescription of supplemental foods.

In addition to the ENPR information already provided, the NFP Interim Rule requires medical documentation for supplemental foods allowed in proposed FP III and an amount prescribed per day. It ensures that the participant's health care provider is aware that WIC is providing supplemental foods that the health care provider has determined are not medically contraindicated by the participant's qualifying medical condition. Requiring the health care provider to designate an amount of WIC formula and the WIC supplemental foods allowed in the participant's diet will help the Certified Professional Authority (CPA) in designing nutrition education and a food package prescription that is appropriate to the participant's medical needs. http://www.nal.usda.gov/wicworks/Learning_Center/FP/Infant_Children_Medical.pdf http://www.nal.usda.gov/wicworks/Learning_Center/FP/Women_Medical.pdf

An ENPR is not authorized for:

- Infants whose only condition is
 - Diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require the use of an exempt infant formula, a non-specific formula or food intolerance
- Women and children who have
 - o A food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages
- Any WIC participant solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition

Documentation of Medical Diagnoses

Non-contract formulas are approved by WIC only when the HCP determines and documents the WIC participant has been diagnosed with any of the Medicode International Classification of Diseases 9th Revision, Clinical Modification (ICD-9-CM) conditions listed on the ENPR form.

WIC Enteral Nutrition and Supplemental Foods Prescription Request (ENPR)

The ENPR is the WIC prescription form that must be completed by a HCP licensed to write prescriptions in Alaska (physician, physician's assistant, or nurse practitioner). Instructions for completing the ENPR are on the back of the ENPR form. WIC does not accept prescriptions written on doctors' prescriptions pads or made via telephone under ordinary circumstances.

A complete ENPR provides the medical documentation needed to approve the issuance of WIC checks to clients to purchase non-contract formula and supplemental foods. The HCP may give the completed ENPR to the WIC participant, fax it to their WIC local agency (LA), or submit it on-line at http://www.hss.state.ak.us/dpa/programs/nutri/E-Forms/WIC_FormulaRequest.asp. The HCPs using the latter option still need to fax or mail a signature form to the LA validating the ENPR. Registered and Licensed Dietitians (RD/LD) complete the *RD/LD & Medicaid Use Only* section. Competent Professional Authority (CPA) paraprofessionals need the guidance of an RD/LD to process an ENPR.

Local Agency RD/LD or CPA Evaluation of an ENPR

If after evaluating an ENPR, the RD/LD or CPA determines that there is no apparent intolerance or health condition contraindicating the issuance of a contract formula, or that the problem is apparently due to improper formula dilution, feeding or storage, the ENPR must be denied. The RD/LD or CPA should let the HCP know the reason for this decision. The decision does not imply that WIC is questioning the HCP clinical judgment but rather, cost constraints and WIC policy limits non-contract formula issuance to serious medical diagnosed conditions only. After consulting with the HCP, there may indeed be sufficient justification for the ENPR approval. Although this may have not been originally documented, the additional justification can be included on the ENPR by WIC staff. State agency nutrition staff can be consulted as needed on questions relating to this policy.

The RD/LD or CPA should document her/his evaluation of the health status of any child prescribed a non-contract formula. References to evaluations on appropriate height and weight for age and whether the child is making progress towards developmental milestones of growth and development must be noted in the WIC chart. Concerns in this or any other area found during the initial evaluation should be noted in the participants WIC chart. The ENPR with the

HCP's original signature must be kept in a central file at the WIC LA clinic. A faxed copy is an acceptable form of original signature.

Appropriate counseling should be offered to the parent or guardian and document it in the participant's file when requests for non-contract formula are denied. Warrants for contract formula should be issued to the participant's parent or guardian. The client may choose to participate in WIC if they wish to continue on the current formula they are using for their child.

Length of Approval for WIC Non-Contract Formula Requests

Local Agencies approve ENPR for the length of time the HCP determines a patient needs the non-contract formula prescription. It is no longer limited to 6 months. Incomplete requests and requests not meeting the criteria listed on the ENPR cannot be approved. WIC will consult the HCP if for any reason there is a need to recommend a change of non-contract formula. A complete ENPR for a WIC client who is on Medicaid can receive one month issuance from WIC, while the Medicaid paperwork is done and starts providing the formula. Issuance may be continued past one month on a case-by-case basis if there are documented problems or delays in getting Medicaid approval. The Certificate of Medical Necessity form approved by Medicaid will now go directly to the WIC Local Agency.

Hardship Provisions

Interim rules allow medical documentation to be telephoned into a CPA at WIC clinics by an HCP licensed by the State to write medical prescriptions. However, such verbal confirmation must be followed quickly by written documentation by the CPA and kept on file at the WIC clinics. This method may only be used until written confirmation is received and only when absolutely necessary to prevent undue hardship to a participant or to prevent a delay in the provision of infant formula that would place the participant at increased nutritional risk.

The LA must obtain written confirmation of the medical documentation within a reasonable amount of time after accepting the initial documentation by telephone (i.e., one or two weeks' time). The written documentation must be kept on file with the initial telephone documentation.

Recordkeeping

Local agencies should keep their non-contract formula issuance rate at \leq 5% or less of the total number of formula prescriptions issued. To find out the quarterly non-contract formula issuance percentage rate, divide.:

NCF Issuance Rate = # Participants Issued Non-contract Formula Quarterly #Participants Issued Any Formula Quarterly (Contract and Non-Contract)

The AKWIC Report #432 has the data needed to calculate the NCF Issuance Rate

Approved Non- Contract Formulas

Infant Formula means all brands of infant formulas that are not covered by a cost containment contract. It does not generate a rebate, and requires medical documentation for its issuance.

Enfamil AR Lipil
Enfamil Gentlease Lipil
Good Start Soy Plus
Good Start Gentle Plus

Exempt Infant Formulas are intended for infants who have inborn errors of metabolism, low birth weight, or who otherwise have unusual medical or dietary problems.

Elecare
Enfacare Lipil
Enfamil Nutramigen Lipil w/Enflora
Neocate Infant Formula
Similac Neosure
Similac Alimentum

Medical Foods are certain enteral products specifically formulated to provide nutritional support for individuals with a diagnosed medical condition when the use of conventional foods is precluded, restricted, or inadequate. They may be nutritionally complete or incomplete, but they must serve the purpose of a food, provide a source of calories and one or more nutrients, and be designed for enteral digestion via an oral or tube feeding.

Carnation Instant Breakfast

Ensure

Ensure with Fiber

Neocate Junior

Pediasure

Pediasure with Fiber

For Children Over One Year of Age the following formulas can be provided with documented medical need through an approved ENPR.

Similac Advance Early Shield

Similac Go and Grow Soy

Isomil Advance Soy

Similac Sensitive

Abbot Nutritional Products, Mead Johnson , Nutricia North America, and Nestle Nutrition web links:

http://www.abbott.com/global/url/content/en_US/20.20.20/product/product_category/Product_Category_Profile_0002.htm

http://www.meadjohnson.com/app/iwp/MJN/Content2.do?dm=mj&id=-8552#q1

https://www.shsna.com/pages/neocate_inf_formula.htm

 $\underline{\text{http://www.verybestbaby.com/}GoodStart/ComfortProteins.aspx?ProductId=108f6251-3dfa-4bf2-9c48-79d2c7e451ea}$

http://www.shsna.com/pages/neocate_oneplus_powder.htm